



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 30 1998

IMCOR™

C/O Robert S. Ura, DDS  
5763 Long Brake Circle  
Edina, Minnesota 55439

Re: K974126

Trade Name: IMCOR™ 3.75 and 5.00mm Externally Hexed,  
Self-Tapping HA Coated Screw Implants with Cover Screw  
Regulatory Class: III  
Product Code: DZE  
Dated: October 13, 1997  
Received: November 3, 1997

Dear Dr. Ura:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

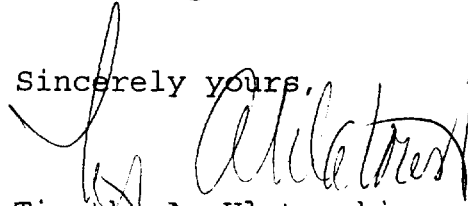
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): N/A

Device Name: IMCOR HA Coated Dental Implant

**Indications For Use:**

IMCOR implants are indicated to replace missing tooth roots for single tooth, partial and fully edentulous patients. The cover screw is used to protect the top of the implant and the internal threads during the healing process.

The INCOR Implant System is designed to become an osseointegrated prostheses allowing the attachment of partial or complete prosthodontic appliances. The use of the INCOR implant is the same as currently accepted uses for dental implants already in the marketplace.

All components are to be used as labeled. Components are not intended to be bent, cast or altered by the clinician.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number KA 74126

Prescription Use ☒

OR

Over-The-Counter Use ☐

(Per 21 CFR 801-109)

(Optional Format 1-2-96)